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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/841,228      04/24/01      DAVIS

S      8567-604US (W)

000570      HM22/0911  
AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA PA 19103

EXAMINER

HOWARD, S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

09/11/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/841,228**

Applicant(s)  
**Davis et al.**

Examiner  
**Sharon Howard**

Art Unit  
**1615**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Jul 3, 2001.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-14 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

20) ☐ Other: \_\_\_\_\_

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**Acknowledged receipt of declaration, fee, priority and IDS filed on 7/3/2001.**

**DETAILED ACTION**

***35 U.S.C. 101 reads as follows:***

***Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.***

***the claimed invention is directed to non-statutory subject matter. In claims 12-14, "The use of" is directed to non-statutory subject matter.***

***Claim Rejections - 35 USC § 112***

1. Claims 1,2,5-7,10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"other than" is indefinite in claims 1,2 and 10, because it is unclear as to what the metes and bounds are in the claim.

The enclosed parentheses around the acronym "NSAID" is not permitted in claims 1 and 2. Also, in claims 5-7 and 11, it is suggested that applicant remove the acronym.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (U.S. Patent No. 6,096,728) in view of Woods et al. (U.S. Patent No. 5,811,425).

Collins discloses a composition and method for treating pain and Parkinson's disease, other inflammatory diseases (col.2, lines 1-29), flurbiprofen and ibuprofen (col.29, lines 12 and 13), non-steroidal antiinflammatory diseases (col.30, lines 52-67 and col.31, lines 1-12). Collins teaches pharmaceutical compositions which are known to be in the form of an emulsion (col.26, lines 33-35) and COX2 inhibitors (col.32, line 26). Collins teaches salicylic acid derivatives, propionic acid derivatives, acetic acid derivatives, fenamic acid derivatives, carboxylic acid derivatives, butyric acid derivatives, oxicams, pyrazoles and pyrazalones having similar analgesic and antiinflammatory properties (col.28, lines 38-67, col.29, lines 1-67, col.30, lines 1-47).

Collins does not teach hydroxylated oil.

However, Woods teaches a hydroxylated oil, castor oil (col.11, lines 14-23) which is known in pharmaceutically acceptable emulsions, and it is known in the art that the oil provides solubilization of the drug. Woods also teaches pharmaceutical compositions comprising emulsions (col.9, lines 65-67, bridging col.10, line 1), vegetable oils (col.10, line 7) and COX-1 and COX-2 (col.9, lines 23-25 and EXAMPLES at col.13 ).

Woods discloses that it is known in the art that the amount of drug to be used will depend upon the route of administration, the severity of the condition being treated and the activity of the particular compound. Woods also teaches that it is known in the art to first use small amounts of the drug than the required amount in order to achieve the desired therapeutic effect of the drug,

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and then to gradually increase the amount of the drug until the desired effect is obtained (col.11, lines 66-67 and col.12, lines 1-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the hydroxylated oil of Woods in the composition of Collins with the expectation of providing a pharmaceutical composition comprising castor oil and a drug dispersed in an emulsion, and one would expect to achieve the same beneficial results.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 746-3121.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record

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includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*Sharon Howard*

Sharon Howard

September 7, 2001

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